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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/628,667 07/28/00 PUTNAM

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HM22/1001

EXAMINER

GARCIA, M

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 10/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

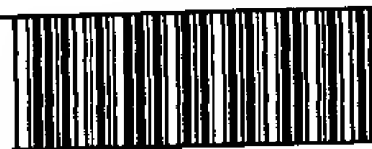
Application No.
09/628,667

Applicant(s)

Putnam et al

Examiner
Maurie E. Garcia, Ph. D.

Art Unit
1627



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-125 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-125 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Jyothsna Venkat, Supervisory Patent Examiner, at (703) 308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-13, drawn to an array of samples, each sample comprising a component-in-common and at least one additional component, classified in various places depending on the identity of the samples/components, for example, any of class 424 or 514 or 540-570; or class 435, DIG 34.
 - II. Claims 14-29, drawn to a method to measure or detect an interaction between components, classified in various places depending on the interaction tested and components, for example, class 436, subclass 501+ or class 435, subclasses 4-7.2.
 - III. Claims 30-43, drawn to a method for testing or optimizing one or more properties of a formulation, classified in various places depending on the property and formulation, for example, class 424, subclasses 439-502.
 - IV. Claims 44-56, drawn to a system to measure or detect an interaction between components, classified in various places depending on the interaction tested, for example, class 435, subclasses 287.1-288.7.
 - V. Claims 57-64, drawn to an array of samples, each sample comprising a sensory-material-in-common and at least one additional component, classified in various places depending on the identity of the samples/sensory material, for example, any of class 424 or 514 or 540-570; or class 435, DIG 34.
 - VI. Claims 65-79, drawn to a method to measure or detect an interaction between a sensory material and another component, classified in various places

depending on the interaction tested and sensory material, for example, class 436, subclass 501+ or class 435, subclasses 4-7.2.

- VII. Claims 80-87, drawn to an array of samples, each sample comprising an agrochemical-in-common and at least one additional component, classified in various places depending on the identity of the samples/agrochemical, for example, any of class 424 or 514 or 540-570; or class 435, DIG 34.
 - VIII. Claims 88-102, drawn to a method to measure or detect an interaction between components (using samples containing an agrochemical-in-common), classified in various places depending on the interaction tested and agrochemical, for example, class 436, subclass 501+ or class 435, subclasses 4-7.2.
 - IX. Claims 103-110, drawn to an array of samples, each sample comprising a component-in-common wherein the component-in-common is an active component of a consumer product formulation or an active component of an industrial product formulation and at least one additional component, classified in various places depending on the identity of the samples/components, for example, any of class 424 or 514 or 540-570; or class 435, DIG 34.
 - X. Claims 111-125, drawn to a method to measure or detect an interaction between components (using samples wherein the component-in-common is an active component of a consumer product formulation or an active component of an industrial product formulation), classified in various places depending on the interaction tested and components, for example, class 436, subclass 501+ or class 435, subclasses 4-7.2.
2. Note that the classification of Groups I-X above has been set forth in very general terms. It is impossible to particularly classify each of the groups due to the fact that the groups encompass an enormous variety of different "components" or "materials" of undefined structure. See also paragraph 13 below.

3. The inventions are distinct, each from the other because of the following reasons:

4. Groups I, V, VII and IX represent separate and distinct products. They differ in respect to their properties, their use and the synthetic methodology for making them. Therefore, they have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, each of the arrays represents a different product. The arrays of Groups V, VII and IX require functional limitations to the array samples that are not required by Group I. Group V requires that the array is made up of samples “comprising a sensory-material-in-common and at least one additional component”; Group VII requires that the array is made up of samples “comprising agrochemical-in-common and at least one additional component”; and Group IX requires that the array is made up of samples “comprising a component-in-common wherein the component-in-common is an active component of a consumer product formulation or an active component of an industrial product formulation and at least one additional component”.

5. Groups II, III, VI, VIII and X are different methods. The methods are different because they use different steps, require different reagents and/or will produce different results. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, each of the methods requires a different reagent (i.e. array) and thus has different steps. The methods of Groups VI, VIII and X require functional limitations to the array samples that are not required by Groups II and III. Groups VI, VIII and X require arrays that comprise a “sensory-material-in-common”; “agrochemical-in-common” and “a component-in-

common wherein the component-in-common is an active component of a consumer product formulation or an active component of an industrial product formulation and at least one additional component”, respectively. Additionally, the method of Group III requires an array of samples comprising “the active component and at least one other component” which is different from all of the other arrays. Furthermore, the method of Group III has steps not required by any of the other methods. This method requires that a “property-result” is generated and that this “property-result” is compared to a baseline or control.

6. Groups I & II; V & VI; VII & VIII and IX & X are all related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, each of the products (arrays) as claimed could be used in a materially different process of using that product. For example, the arrays could be used as a starting material for creation of further arrays (containing additional components).

7. Groups II and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP

§ 806.05(e)). In this case, the process of Group II could be carried out by hand (i.e. manual analysis of the array of samples).

Also, if it is argued that the invention of Group I is somehow related to the system of Group IV, it is noted that the array of Group I could be used in other processes, carried out by other apparatuses, such as a starting material for creation of further arrays (containing additional components made on an automatic synthesizer, for example).

8. The system of Group IV is not related to the methods of Groups III, VI, VIII and X as these methods do not require the same starting materials and/or steps as set forth for the claimed system. There is also no relationship between the arrays of Groups V, VII and IX and the system of Group IV. See also paragraph 5 above.

9. The methods of Groups III, VI, VIII and X are not related to the product of Group I. The array of Group I is not required for the methods of Groups III, VI, VIII and X and the inventions are not disclosed as capable of use together. See also paragraphs 4 & 5 above.

10. The methods of Groups II, III, VIII and X are not related to the product of Group V. The array of Group V is not required for the methods of Groups II, III, VIII and X and the inventions are not disclosed as capable of use together. See also paragraphs 4 & 5 above.

11. The methods of Groups II, III, VI and X are not related to the product of Group VII. The array of Group VII is not required for the methods of Groups II, III, VI and X and the inventions are not disclosed as capable of use together. See also paragraphs 4 & 5 above.

12. The methods of Groups II, III, VI and VIII are not related to the product of Group IX. The array of Group IX is not required for the methods of Groups II, III, VI and VIII and the inventions are not disclosed as capable of use together. See also paragraphs 4 & 5 above.

13. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. Please note that even though some of these groups could be classified in the same class or subclass, this has no effect on the non-patent literature search. Different methods and products would require completely different searches in these databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

14. This application contains claims directed to patentably distinct species of the claimed invention for **Groups I - X**. Election is required as follows.

15. If applicant elects the invention of **Group I**, applicant is required to elect from the following patentably distinct species. Note an election from EACH subgroup below is required. Claims 1, 3-8 and 11-13 are generic to this group.

Subgroup A: Type and identity of component-in-common (e.g. claim 2)
First, an election from the "type" of component-in-common is required as follows:

1. Pharmaceutical
2. Dietary supplement
3. Alternative medicine
4. Nutraceutical

Next, Applicant is required to elect, for purposes of search, a **specific** component-in-common. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure).

Subgroup B: Action/identity of component (e.g. claims 9 and 10)

Applicant is required to elect a specific action and identity for the component as set forth in claims 9 and 10. For example, bioadhesive excipient that alters the rate of bioavailability.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

16. If applicant elects the invention of **Group II**, applicant is required to elect from the following patentably distinct species. Note an election from EACH subgroup below is required. Claims 14, 17, 20 and 22-29 are generic to this group.

Subgroup A: Type and identity of component-in-common (e.g. claim 15)
First, an election from the "type" of component-in-common is required as follows:

1. Pharmaceutical
2. Dietary supplement
3. Alternative medicine
4. Nutraceutical

Next, Applicant is required to elect, for purposes of search, a specific component-in-common. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure).

Subgroup B: Property tested (e.g. claim 16)

Applicant is required to elect a specific property that is tested from those set forth in claim 16.

Subgroup C: Type of analysis

- | | |
|---|---------------|
| 1. To detect or measure the interaction | claim 18 |
| 2. To detect a lack of the interaction | claim 19 & 21 |

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

17. If applicant elects the invention of **Group III**, applicant is required to elect from the following patentably distinct species. Note an election from EACH subgroup below is required. Claims 30, 33-35 and 36-43 are generic to this group.

Subgroup A: Type and identity of active component (e.g. claim 31)

First, an election from the "type" of active component is required as follows:

1. Pharmaceutical
2. Dietary supplement
3. Alternative medicine
4. Nutraceutical

Next, Applicant is required to elect, for purposes of search, a specific active component. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure).

Subgroup B: Property tested (e.g. claim 32)

Applicant is required to elect a specific property that is tested from those set forth in claim 32.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

18. If applicant elects the invention of **Group IV**, applicant is required to elect from the following patentably distinct species. Note an election from EACH subgroup below is required. Claims 44, 45, 48, 49 and 50-56 are generic to this group.

Subgroup A: Type and identity of component-in-common (e.g. claim 46)

First, an election from the "type" of component-in-common is required as follows:

1. Pharmaceutical
2. Dietary supplement
3. Alternative medicine
4. Nutraceutical

Next, Applicant is required to elect, for purposes of search, a **specific** component-in-common. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure).

Subgroup B: Property tested (e.g. claim 47)

Applicant is required to elect a specific property that is tested from those set forth in claim 47.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

19. If applicant elects the invention of **Group V**, applicant is required to elect from the following patentably distinct species. Claims 57-64 are generic to this group.

Subgroup: Identity of sensory-material-in-common

Applicant is required to elect, for purposes of search, a specific sensory-material-in-common. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

20. If applicant elects the invention of **Group VI**, applicant is required to elect from the following patentably distinct species. Note an election from EACH subgroup below is required. Claims 65, 67, 70 and 72-79 are generic to this group.

Subgroup A: Identity of sensory-material-in-common

Applicant is required to elect, for purposes of search, a specific sensory-material-in-common. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure).

Subgroup B: Property tested (e.g. claim 66)

Applicant is required to elect a specific property that is tested from those set forth in claim 66.

Subgroup C: Type of analysis

- | | |
|---|---------------|
| 1. To detect or measure the interaction | claim 68 |
| 2. To detect a lack of the interaction | claim 69 & 71 |

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

21. If applicant elects the invention of **Group VII**, applicant is required to elect from the following patentably distinct species. Claims 80-87 are generic to this group.

Subgroup: Identity of agrochemical-in-common

Applicant is required to elect, for purposes of search, a specific agrochemical-in-common. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

22. If applicant elects the invention of **Group VIII**, applicant is required to elect from the following patentably distinct species. Note an election from EACH subgroup below is required. Claims 88, 90, 93, 95-102 are generic to this group.

Subgroup A: Identity of agrochemical-in-common

Applicant is required to elect, for purposes of search, a specific agrochemical-in-common. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure).

Subgroup B: Property tested (e.g. claim 89)

Applicant is required to elect a specific property that is tested from those set forth in claim 89.

Subgroup C: Type of analysis

- | | |
|---|---------------|
| 1. To detect or measure the interaction | claim 91 & 94 |
| 2. To detect a lack of the interaction | claim 92 |

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

23. If applicant elects the invention of **Group IX**, applicant is required to elect from the following patentably distinct species. Claims 103-110 are generic to this group.

Subgroup: Identity of component-in-common

Applicant is required to elect, for purposes of search, a specific component-in-common. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

24. If applicant elects the invention of **Group X**, applicant is required to elect from the following patentably distinct species. Note an election from EACH subgroup below is required. Claims 111, 113, 116 and 118-125 are generic to this group.

Subgroup A: Identity of component-in-common

Applicant is required to elect, for purposes of search, a specific component-in-common. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure).

Subgroup B: Property tested (e.g. claim 112)

Applicant is required to elect a specific property that is tested from those set forth in claim 112.

Subgroup C: Type of analysis

- | | |
|---|-----------------|
| 1. To detect or measure the interaction | claim 114 & 117 |
| 2. To detect a lack of the interaction | claim 115 |

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

25. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

26. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

27. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

28. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

29. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

30. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim


remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

31. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:00 to 6:30 and alternate Fridays.

33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie E. Garcia, Ph.D.
September 27, 2001



MAURIE E. GARCIA, Ph.D.
PATENT EXAMINER